

## **Dynavax's HEPLISAV-B™ [Hepatitis B Vaccine (Recombinant), Adjuvanted] Recommended by CDC Advisory Committee on Immunization Practices for the Prevention of Hepatitis B in Adults**

### **HEPLISAV-B is the First and Only Two-Dose Vaccine in the U.S. for Hepatitis B Prevention in Adults**

BERKELEY, Calif., Feb. 21, 2018 (GLOBE NEWSWIRE) -- Dynavax Technologies Corporation (NASDAQ:DVAX) today announced that the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted unanimously in favor of including HEPLISAV-B on its list of ACIP recommended products for use to vaccinate adults against hepatitis B. HEPLISAV-B was approved by the U.S. Food and Drug Administration (FDA) in November 2017 for the prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

"With the ACIP's recommendation, HEPLISAV-B has cleared an important milestone needed to position Dynavax to meet our long-term commercial goals. Additionally, this recognition emphasizes the important role of HEPLISAV-B in the prevention of hepatitis B infection in adults, reinforcing our belief that our unique two-dose vaccine with demonstrated higher rates of protection versus ENGERIX-B, and a safety profile similar to three-dose vaccines, will become the new standard of care for adults," said Eddie Gray, chief executive officer of Dynavax.

The receipt of the ACIP recommendation is a key step in providing patients with broad access to HEPLISAV-B. Medical policies of many insurance plans and institutions require ACIP recommendation before a vaccine is covered or available to their patients. Dynavax commercially launched HEPLISAV-B in the United States in January 2018, and announced yesterday that the field sales team will actively begin selling HEPLISAV-B next week. The vaccine can be ordered through a network of distributors. The company is working with an extensive network of group purchasing organizations and government entities to help ensure adult patients have access to HEPLISAV-B. A list of the current distributors in the Dynavax network can be accessed by calling 1-84-HEPLISAV (1-844-375-4728). Dynavax is also working to support broad reimbursement of HEPLISAV-B by insurance plans. Proactive payer outreach is currently ongoing and will include the ACIP recommendation for HEPLISAV-B once it is approved by the CDC and U.S. Department of Health and Human Services (HHS).

The ACIP recommendation will be reviewed and approved by the CDC before being published in the *Morbidity and Mortality Weekly Report (MMWR)*.

Please see Important Safety Information below. For more information about HEPLISAV-B, visit <http://heplisavb.com/>.

#### **About Hepatitis B**

Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV,<sup>i</sup> and transmission is on the rise. Hepatitis B is a major public health issue in the United States, where an estimated 20,000 new infections occur each year, and approximately 850,000 people are currently living with this chronic disease.<sup>i</sup> In 2015, new cases of acute hepatitis B increased by more than 20 percent nationally.<sup>ii</sup> There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The CDC recommends that individuals at high risk for hepatitis B infection due to their jobs, lifestyle, living situations and travel to certain areas be immunized.<sup>iii</sup> Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 60 and older with diabetes at their physician's discretion.<sup>iv</sup> Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.<sup>v</sup>

#### **About HEPLISAV-B**

HEPLISAV-B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV-B.

#### **Indication and Use**

HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

## Important Safety Information (ISI)

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%) and headache (8% to 17%).

For full **Prescribing Information** for HEPLISAV-B, [click here](#).

## About Dynavax

Dynavax is a commercial-stage biopharmaceutical company focused on leveraging the power of the body's innate and adaptive immune responses through toll-like receptor (TLR) stimulation. Dynavax discovers and develops novel vaccines and immuno-oncology therapeutics. The Company's first commercial product, HEPLISAV-B, a hepatitis B vaccine for adults, is approved in the United States. Dynavax's lead immunotherapy product, SD-101, is an investigational cancer immunotherapeutic currently being evaluated in Phase 1/2 studies and its second cancer immunotherapeutic, DV281, is in Phase 1 development. For more information, visit [www.dynavax.com](http://www.dynavax.com).

## Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the commercialization of HEPLISAV-B. These statements are subject to a number of risks and uncertainties that could cause actual results to differ materially, including whether the company will be able to continue building the commercial infrastructure required to successfully launch HEPLISAV-B; whether payers will provide timely reimbursement for HEPLISAV-B; whether prescribers and other key decision-makers will switch to HEPLISAV-B; and whether potential claims against us, including those based on patent rights of others, will result in an injunction against sales or otherwise impact commercialization and sales. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Dynavax in general, see risks detailed in the "Risk Factors" section of our most recent current periodic report filed with the SEC. These statements represent our estimates and assumptions only as of the date of this press release. We do not undertake any obligation to update publicly any such forward-looking statements, even if new information becomes available. Information on Dynavax's website at [www.dynavax.com](http://www.dynavax.com) is not incorporated by reference in our current periodic reports with the SEC.

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<sup>i</sup> CDC. <https://www.cdc.gov/hepatitis/hbv/bfaq.htm>.

<sup>ii</sup> CDC. <https://www.cdc.gov/hepatitis/statistics/2015surveillance/index.htm#tabs-5-8>. Fig 3.2

<sup>iii</sup> CDC. <https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>.

iv CDC. [https://www.cdc.gov/diabetes/pubs/pdf/hepb\\_vaccination.pdf](https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf).

v CDC. <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

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